

510(k) Summary**MAY 09 2013****1. Contact Details**

Applicant Name: SeaSpine, Inc. (A subsidiary of Integra LifeSciences Corporation)

Address: 2302 La Mirada Drive, Vista, CA 92081

Phone number: (760) 727-8399

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Contact person: Jeff Brittan, - Director, Engineering

Email address: jeff.brittan@integralife.com

Date Prepared: March 18, 2013

2. Device Name

Trade Name: Integra® Laminoplasty System

Common Name: Lamioplasty Plating System

Classification Name: Spinal Interlaminar Fixation Orthosis (21 CFR 888.3050)

Product Code: NQW, Class II

3. Legally Marketed Predicate Device(s)

510(k) Number	Product Code	Trade Name	Manufacturer
K091623	NQW	NuVasive (Leverage) Laminoplasty Fixation System	NuVasive, Inc.
K050082	NQW	CENTERPIECE™ Plate Fixation System	Medtronic Sofamore Danek USA, Inc.

4. Device Description

The Integra® Laminoplasty System consists of plates and screws that are attached to the lamina after a laminoplasty procedure; the system is manufactured from Titanium 6Al-4V ELI per ASTM F136. Implants are available in a range of sizes and shapes, as well as in various screw hole configurations to accommodate variations in patient anatomy. The system also includes instruments to assist with implantation, and a tray for organization and storage

5. Intended Use/Indications for use

The Integra® Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) after laminoplasty procedures. The Integra® Laminoplasty System is used to hold the allograft material in place in order to prevent the allograft material from expulsion, or impinging the spinal cord.

6. Substantial Equivalence Comparison

The Integra® Laminoplasty System is substantially equivalent to the cited predicate devices in areas including intended use/indications for use, technological characteristics (operating principle, design, materials, sterility, manufacturing, etc.) and performance (mechanical safety).

7. Non-clinical Testing

The Integra® Laminoplasty System demonstrated equivalent performance to the predicate systems through static and dynamic mechanical testing per ASTM F2193.

8. Clinical Testing

No clinical testing was required to demonstrate equivalence.

9. Conclusions

The submitted data demonstrate that the Integra® Laminoplasty System is as safe, as effective, and performs at least as safely and effectively as the cited legally marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 9, 2013

SeaSpine, Incorporated
Mr. Jeff Brittan
2302 La Mirada Drive
Vista, California 92081

Re: K130830

Trade/Device Name: Integra® Laminoplasty System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminar fixation orthosis
Regulatory Class: Class II
Product Code: NQW
Dated: March 18, 2013
Received: March 26, 2013

Dear Mr. Brittan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

For 
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K130830

Device Name: Integra® Laminoplasty System

Indications for Use:

The Integra® Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) after laminoplasty procedures. The Integra® Laminoplasty System is used to hold the allograft material in place in order to prevent the allograft material from expulsion, or impinging the spinal cord.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)

Division of Orthopedic Devices

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